



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
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June 4, 2001

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Gary H. Schlatter, President and C.E.O.
OraLabs, Inc.
2901 S. Tejon Street
Englewood, Colorado 80110

Ref. # DEN-01-33

Dear Mr. Schlatter:

This letter is in reference to the promotion, marketing, and distribution of "Cholesterx" by your firm. The labeling for "Cholesterx" (carton and insert), collected during the inspection of your firm on January 2, 2001, claims it "lowers total cholesterol ... Cholesterx is a powder made from Chinese rice fermented with red yeast. The rice formula contains a natural form of lovastatin, the active ingredient in lowering cholesterol levels ... Red yeast rice works through the use of HMG Co-A Reductase [sic] Inhibitors ... Red Yeast Rice has been shown to: • Reduce total cholesterol levels 14-17% • Reduce LDL levels 13-20% • Reduce triglycerides 18-24% • Increase HDL levels 8-15%..."

Certificates of analysis provided by (~~X~~ ~~X~~ ~~X~~ ~~X~~) the manufacturer of the Red Yeast Rice Extract, which is used in "Cholesterx," state that the product contains "0.5% lovastatin." The Agency's position is that red yeast rice products that contain lovastatin are subject to regulation as drugs and are not dietary supplements. This position has been affirmed by the March 20, 2001, decision by the U.S. District Court of the District of Utah which dismissed the case brought against the Agency by Pharmanex, Inc., a company marketing a similar product containing red yeast rice and lovastatin.

"Cholesterx" is a drug under section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Moreover, "Cholesterx" is a "new drug" [Section 201(p) of the Act] because there is no evidence that this product is generally recognized as safe and effective for its intended uses. Since this product is a "new drug", it may not be legally marketed in the United States without an approved New Drug Application [Section 505 of the Act].

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This drug product is misbranded [sections 502(f)(1) and (2) of the Act] because its labeling fails to bear adequate directions for use for the conditions for which it is offered, and adequate warnings as required by the Act. The drug is also misbranded because the labeling is false and misleading as it suggests that the product is safe and effective for its intended use when this has not been established [section 502(a) of the Act].

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug and Cosmetic Act provides for the seizure of illegal products and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

Your reply should be sent to the attention of Ms. Shelly L. Maifarth, Compliance Officer, at the above letterhead address.

Sincerely,


Thomas A. Allison
District Director

Cc:

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